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United States Patent [19]**Modak et al.**[11] **Patent Number:** **5,772,640**[45] **Date of Patent:** **Jun. 30, 1998**[54] **TRICLOSAN-CONTAINING MEDICAL DEVICES**[75] **Inventors:** **Shanta Modak, River Edge, N.J.;
Lester Sampath, Nyack, N.Y.**[73] **Assignee:** **The Trustees of Columbia University
of the City of New York, New York,
N.Y.**[21] **Appl. No.:** **583,239**[22] **Filed:** **Jan. 5, 1996**[51] **Int. Cl.⁶** **A61M 5/32**[52] **U.S. Cl.** **604/265; 424/422; 623/1;
428/35.7**[58] **Field of Search** **604/265, 264;
428/35.7, 36.9; 606/76; 424/422; 623/1**[56] **References Cited****U.S. PATENT DOCUMENTS**

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Attorney, Agent, or Firm—Baker & Botts, L.L.P.[57] **ABSTRACT**

The present invention relates to polymeric medical articles contained the antiinfective agents chlorhexidine and triclosan. It is based, at least in part, on the discovery that the synergistic relationship between these compounds permits the use of relatively low levels of both agents, and on the discovery that effective antimicrobial activity may be achieved when these compounds are contained in either hydrophilic or hydrophobic polymers.

30 Claims, No Drawings

1. A hydrophilic polymeric medical article which has been impregnated, coated, or impregnated and coated with a treatment solution comprising (i) between about 1 and 10 percent of a hydrophilic polymer; (ii) between 1 and 5 percent of an antiinfective agent selected from the group consisting of chlorhexidine free base, a chlorhexidine salt, and a chlorhexidine derivative; and (iii) between 0.5 and 5 percent of triclosan.

2. The medical article of claim 1 which is fabricated from a hydrophilic polymer selected from the group consisting of natural rubber latex and biomedical polyurethane.

3. The medical article of claim 1 wherein the hydrophilic polymer in the treatment solution is a biomedical polyurethane.

4. The medical article of claim 2 wherein the hydrophilic polymer in the treatment solution is a biomedical polyurethane.

5. A hydrophilic polymeric medical article which has been impregnated, coated, or impregnated and coated with a treatment solution comprising (i) between about 1 and 10 percent of a hydrophobic polymer (ii) between 1 and 5 percent of an antiinfective agent selected from the group consisting of chlorhexidine free base, a chlorhexidine salt, and a chlorhexidine derivative; and (iii) between 0.5 and 5 percent of triclosan.

6. The medical article of claim 5, further comprising silver sulfadiazine.

7. The medical article of claim 6 wherein the hydrophobic polymer is a biomedical silicone polymer.

8. The medical article of claim 6 wherein the hydrophobic polymer is a silicone-polyurethane copolymer.

9. The medical article of claim 5 which is a catheter.

10. The catheter of claim 9 which is an intravenous catheter.

11. The catheter of claim 10 which is fabricated from a biomedical polyurethane.

12. The catheter of claim 11 wherein the hydrophobic polymer in the solution is a biomedical silicone-polyurethane copolymer.

13. The medical article of claim 5 which is fabricated from a hydrophilic polymer selected from the group consisting of natural rubber latex and biomedical polyurethane.

14. The medical article of claim 13 wherein the hydrophobic polymer in the treatment solution is a biomedical silicone polymer.

15. The medical article of claim 13 wherein the hydrophobic polymer in the treatment solution is a silicone-polyurethane copolymer.

16. The medical article of claim 5 wherein the hydrophobic polymer in the treatment solution is a biomedical silicone polymer.

17. The medical article of claim 5 wherein the hydrophobic polymer in the treatment solution is a silicone-polyurethane copolymer.

18. A hydrophobic polymeric medical article which has been impregnated, coated, or impregnated and coated with a treatment solution comprising (i) between about 1 and 10 percent of a hydrophobic polymer (ii) between 1 and 5 percent of an antiinfective agent selected from the group consisting of chlorhexidine free base, a chlorhexidine salt,

and a chlorhexidine derivative; and (iii) between 0.5 and 5 percent of triclosan.

19. The medical article of claim 18 which is fabricated from a hydrophobic polymer selected from the group consisting of polytetrafluoroethylene, Dacron, which is a polyethylene terephthalate polyvinylchloride, biomedical silicone polymer, and silicone polyurethane copolymer.

20. The medical article of claim 19 wherein the hydrophobic polymer in the treatment solution is a biomedical silicone polymer.

21. The medical article of claim 19 wherein the hydrophobic polymer in the treatment solution is a silicone-polyurethane copolymer.

22. The medical article of claim 18 wherein the hydrophobic polymer in the treatment solution is a biomedical silicone polymer.

23. The medical article of claim 18 wherein the hydrophobic polymer in the treatment solution is a silicone-polyurethane copolymer.

24. A method for rendering a silicone catheter antiinfective, comprising:

(1) placing the silicone catheter in an impregnating solution comprising (a) a solvent which causes the catheter to swell; (b) between 1 and 5 percent of an antiinfective agent selected from the group consisting of chlorhexidine free base, a chlorhexidine salt, and a chlorhexidine derivative; (c) between 0.5 and 5 percent of triclosan; and (d) between 1 and 10 percent of a biomedical polymer;

(2) soaking the catheter in the impregnating solution for a period of time sufficient to allow the catheter to swell;

(3) removing the catheter from the impregnating solution; and

(4) drying the catheter.

25. The method of claim 24, wherein the biomedical polymer is a biomedical silicone polymer.

26. The method of claim 24, further comprising the step of dipping the catheter, after drying according to step (4), into a second coating solution comprising a biomedical polymer.

27. The method according to claim 26, wherein the biomedical polymer in both the impregnating solution and the second coating solution is a biomedical silicone polymer.

28. A hydrophobic polymeric medical article which has been impregnated, coated, or impregnated and coated with a treatment solution comprising (i) between about 1 and 10 percent of a hydrophilic polymer; (ii) between 1 and 5 percent of an antiinfective agent selected from the group consisting of chlorhexidine free base, a chlorhexidine salt, and a chlorhexidine derivative; and (iii) between 0.5 and 5 percent of triclosan.

29. The medical article of claim 28 which is fabricated from a hydrophobic polymer selected from the group consisting of polytetrafluoroethylene, Dacron, which is a polyethylene terephthalate polyvinylchloride, biomedical silicone polymer, and silicone polyurethane copolymer.

30. The medical article of claim 28 wherein the hydrophilic polymer is a biomedical polyurethane.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,772,640

DATED : June 30, 1998

INVENTOR(S) : Modak et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 16, line 54, "Dacron, which" should read "Dacron which"; and

Col. 16, line 55, "terephthalate polyvinylchloride" should read -- terephthalate, polyvinylchloride --.

Signed and Sealed this
Fourteenth Day of September, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,772,640

DATED : June 30, 1998

INVENTOR(S) : Modak et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page:

Item [57], line 2 of Abstract, "contained" should read -- comprising --; and

Item [57], line 7 of Abstract, "contained" should read -- comprised --.

Signed and Sealed this
Fourth Day of July, 2000

Attest:



Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks